510(k) Summary according to 807.92(c)
CapLOX II Pedicle Screw System

APR 13 2012

Date: January 16, 2012

Submitter Contact: Dale Mitchell
Captiva Spine
967 Alternate A1A #1
Jupiter, FL 33477
877-772-5571
866-318-3224

Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
612-281-5505
richj@s-pineconsulting.com

Trade Name: CapLOX II Pedicle Screw System
Product Class: Class II
Classification: 888.3070 Pedicle Screw Spinal System
Product Codes: MNI, MNH
Panel Code: 87

Predicate Device(s): CapLOX II Pedicle Screw System (K111115, SE 9-13-11)

Reason for this Submission: This Special 510(k) involves several changes to the previously cleared CapLOX II System.

- Added recess to thread start at top of tulip
- Tulip head changed to one universal size that falls between the small & large sizes already cleared
- Tulip head position of area to hold cap adjusted to fit universal design
- Set Screw changed to one universal size between small & large sizes already cleared
- Added truncated thread to locking screw
- Hex size increased on locking screw
- Locking cap changed to one universal size between small & large sizes already cleared
- Screw head height has been reduced to adapt to universal tulip
- Hex size and depth increased
- Increased cutting flutes from 1 to 3 on tip of the screw
- Added dual lead thread to screw
- Increased cannulation size from 1.3mm to 1.47mm to accommodate stiffer guide wire
- Increased minor diameter by .13mm to maintain area moment of inertia relationship
- Screw size offering changed to offer intermediate diameters within the previously cleared offering range
- Added new rod lengths to set offering
- Added pre-curved rods to set offering

Indications for Use/Intended Use: The CapLOX II Spinal System is a posterior, non-cervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the CapLOX II Spinal System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral, L5-S1 vertebra, who are receiving fusion by autogenous bone graft only, who are having the device attached to the lumbar and sacral spine (levels may be from L3 to the sacrum/ilium), who are having the device removed after the attainment of a solid fusion.

Device Description: The CapLOX II Pedicle Screw System is a permanent implant device made from a titanium alloy TI 6AL4V-ELI. It is to be implanted from the posterior approach. The screws are available in diameters from 4.9-8.0mm and in lengths from 30-55mm. Rods are available in 5.5mm diameter, as either straight rods available in lengths from 30-500mm or pre-curved rods available in lengths from 30-120mm. The system includes a set screw, tulip heads, a cap and cross connectors to complete the assembly.

Performance Testing: This Special 510(k) involved minor changes to the tulip head. Therefore, new performance testing per ASTM F1798 was completed at an independent laboratory. Test results confirm that the changes did not alter the mechanical characteristics of the system.

Conclusion: Captiva Spine concludes that the changes to the system do not introduce any new risks and therefore, the system is Substantially Equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 13 2012

Captiva Spine
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
13540 Guild Ave
Apple Valley, MN 55124

Re: K120292
Trade/Device Name: CapLOX II Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: March 14, 2012
Received: March 15, 2012

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K120292

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120292